



STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR MEDICAL SERVICES



## Office of Pharmacy Services Prior Authorization Criteria

**ZEPATIER™ (elbasvir and grazoprevir)**

**Effective 2/24/2016**

[Prior Authorization Request Form](#)  
[Prior Authorization Continuation Request Form](#)  
[Patient Consent Form](#)  
[Preferred HepC Regimens \(Attachment A\)](#)

*Zepatier™ is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults.*

### **Criteria for Approval**

- 1) **All requests for Zepatier must clearly indicate why the patient cannot take a preferred medication indicated for their HCV genotype (See [Attachment A](#) for a list of preferred regimens per genotype); AND**
- 2) **All documentation must be fully completed, including the patient consent form. A fibrosis score substantiated by a validated evidence-based method must be reported when requesting prior authorization; AND**
- 3) **Patient must have a documented **fibrosis level ≥ F3**; AND**
- 4) **Patient must be eighteen (18) years of age or older; AND**
- 5) **Zepatier must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; AND**
- 6) **Patient must be diagnosed with chronic Hepatitis C Genotype 1 or 4; AND**
- 7) **Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months, as indicated by their signature on the Patient Consent form; AND**
- 8) **Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;**

### **Duration of Approval**

- Initial approval is for 6 weeks and requires submission of the starting HCV RNA level (*See Table 1 for the list of accepted regimens*).
- Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued



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abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**

**Table 1 Accepted Regimens and Treatment Duration for HCV Therapy**

Diagnosis	Approved Regimen	Duration
Genotype 1a - Treatment-naïve or PegIFN/RBV-experienced <sup>1</sup> without baseline NS5A polymorphisms <sup>2</sup>	Zepatier	12 weeks
Genotype 1a - Treatment-naïve or PegIFN/RBV-experienced <sup>1</sup> with baseline NS5A polymorphisms <sup>2</sup>	Zepatier + ribavirin	16 weeks
Genotype 1b - Treatment-naïve or PegIFN/RBV-experienced <sup>1</sup>	Zepatier	12 weeks
Genotype 1a/1b - PegIFN/RBV/PI-experienced <sup>3</sup>	Zepatier + ribavirin	12 weeks
Genotype 4 - Treatment-naïve	Zepatier	12 weeks
Genotype 4 - PegIFN/RBV-experienced <sup>1</sup>	Zepatier + ribavirin	16 weeks

<sup>1</sup>Peginterferon alfa + ribavirin

<sup>2</sup>Polymorphisms at amino acid positions 28, 30, 31 or 93.

<sup>3</sup>Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor.

**ALL OTHER REGIMEN REQUESTS WILL BE CONSIDERED ON A CASE-BY-CASE BASIS**

**Diagnostic/Disease Severity Evidence (must be attached to request)**

- 1) Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
  - a. Cirrhotic features on imaging (MRI, ultrasound, or CT)
  - b. Ascites
  - c. Esophageal varices
  - d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/ $\mu$ L), and coagulopathy (INR > 2)

**Criteria for Denial**

- 1) Requests submitted with incomplete documentation will be denied.
- 2) Failure to report a fibrosis score.
- 3) Evidence exists that the patient has abused any illicit substance or alcohol in the past three (3) months.



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- 4) Patient has severe renal impairment (eGFR < 30 mL/min/1.73m<sup>2</sup>) or end stage renal disease (ESRD) requiring hemodialysis.
- 5) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

### **Additional Considerations**

- 1) It is highly recommended that the patient vaccinated against Hepatitis A and Hepatitis B.
- 2) **For HCV/HIV co-infections all requests must be reviewed for drug-drug interactions prior to approval. Please submit a list of the patient's current HIV regimen along with your request for coverage of Zepatier.**
- 3) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.
- 4) Lost or stolen medication replacement request will not be authorized.
- 5) Zepatier was granted [breakthrough therapy designation](#) for the treatment of chronic HCV genotype 1 infection in patients with end stage renal disease on hemodialysis and for the treatment of chronic HCV genotype 4 infection. Breakthrough therapy designation is a program designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint.

### **References**

- 1) Zepatier [package insert]. Merck, January, 2016.
- 2) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: <http://www.hcvguidelines.org/>. Accessed February 16, 2016.
- 3) Poynard T, Ratziu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis c: detection and significance. *Semin Liver Dis.* 2000;20(1). Retrieved from [www.medscape.com](http://www.medscape.com). Accessed February 26, 2014.
- 4) Heidelbaugh JJ and Bruderly M. Cirrhosis and Chronic Liver Failure: Part I. Diagnosis and Evaluation. *Am Fam Physician.* 2006 Sep 1;74(5):756-762.